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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/835,482	04/08/1997	ALAN A. RUBIN	002	5100

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	33

DATE MAILED: 04/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/835,482	RUBIN, ALAN A.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 January 2003 (paper no.32)* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,11,12 and 17-23* is/are pending in the application.

4a) Of the above claim(s) *19 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,11,12,17,18 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the Application

Acknowledgement is made of the receipt of the Response to Restriction Requirement filed 01/21/03, whereby applicant elected Group I with traverse.

Claims 19 and 20 (Group II) were withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected subject matter, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 32.

Claims 1, 11, 12, 17, 18 and 21-23 are pending. Claims 1, 11, 12 17, 18 and 21-23 are rejected.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 11, 17 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 11, line 1, contains the phrase, "*the oral dosage formulation <u>including</u> a bilayer tablet or pellet*". The term "*<u>including</u>*" renders the claim indefinite because it is

unclear as to which additional components asides from the bilayer tablet or pellet are included or added to the oral dosage formulation. It is suggested that the term "including" be either positively recited or deleted.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1, 11, 12, 17, 18 and 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dempski et al. (US Pat. No. 4,900,755, collectively, "Dempski") in view of Conte et al. (US Pat. No.5,738,874, collectively, "Conte").

Dempski teaches an oral controlled release formulation comprising a combination of carbidopa and levodopa useful for the treatment of Parkinson's disease

whereby treatment of parkinsonism with the controlled release formulation provides several advantages over treatment with the standard carbidopa/levodopa combinations previously employed (see Abstract and col. 1, lines 1-60). Dempski teaches that the controlled release tablet of carbidopa/levodopa of the invention is a matrix or monolithic drug delivery system containing carbidopa and levodopa as the active ingredients. The system consists of the two drugs, uniformly dispersed in a polymer vehicle at a concentration that is greater than either drug solubility in the polymer vehicle which is either a single or a combination of polymers. The art recognizes the importance of treating Parkinson's disease with a dosage form which prevents the emergence of "wearing-off" and"on-off" phenomena. The combination of carbidopa and levodopa in a controlled release preparation can help to prevent the emergence of "wearing-off" and"on-off" phenomena and the combination of carbidopa and levodopa was designed to obviate or at least alleviate problems associated with standard combination therapy (see col. 1, line 44 through col. 2, line 52).

With regards to the concentration of the drugs, Dempski teaches overlapping ranges at col. 3, lines 45-60. For instance, in a typical formulation, levodopa can be in the range of 20-200 mg, and more preferably in a range of 100-400 mg. Carbidopa can be contained in the range of 5-300 mg, more preferably, 25-100 mg. These ranges read on the applicant's claimed ranges. Furthermore, it is deemed obvious to one of ordinary skill in the art that suitable ranges could be determined through routine or manipulative experimentation.

Specific examples (1-7) of the carbidopa/levodopa formulation are demonstrated at col. 3, line 45 through col.5, line 60.

Dempski teaches a single-layered tablet form (controlled release layer) and is deficient only in the sense that he does not teach a two-layered or bi-layered tablet dosage form that comprises an immediate release layer and a sustained release layer.

Conte teaches a pharmaceutical tablet capable of liberating one or more drugs at different release rates wherein the tablet consists of a first layer containing one or more drugs with immediate or controlled release formulation and a second layer containing one or more drugs, either equal to or different from those of the first layer, with a slow release formulation (see abstract). An optional barrier-type coating layer can be placed between the first and second layers. Conte also teaches various drugs, which can be present in the formulation, including both carbidopa and levodopa, and teaches combination therapy with both carbidopa and levodopa in a formulation with multiple release profiles (see cols. 2 and 3 and claim 6).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the teachings of Conte within the teachings of Dempski because Conte teaches a bi-layered pharmaceutical tablet comprising various drugs (i.e., carbidopa, levodopa) wherein the first layer contains one or more drugs with immediate or controlled release formulation and a second layer containing one or more drugs with slow release formulation and similarly Dempski teaches an oral controlled release formulation comprising a combination of carbidopa and levodopa useful for the

treatment of Parkinson's disease. The expected result would be an improved two-layered pharmaceutical dosage form for the effective treatment of Parkinson's disease, as similarly desired by the applicant.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (703) 308-4429. The examiner can normally be reached on Monday through Friday from 7:00A.M. to 4:30P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

hns
April 07, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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